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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,669	07/13/2001	Charles S.H. Young	0575/62530-A/JPW/ADM	5175

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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,669	YOUNG ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1- 16* is/are pending in the application.

4a) Of the above claim(s) *6- 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 -5* is/are rejected.

7)☒ Claim(s) *2- 4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that there is no burden on the examiner to search the remaining groups. This is not found persuasive because each of the remaining groups is drawn to different methods that treat different populations and have a different end results.

Claims 6- 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1- 5 are under consideration in this office action.

Claim Objections

Claims 2- 4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A limitation of claim 1, recites "neither the gene product of the E1A region nor the gene product of the E1B region is expressed" and therefore, expression of either one or both of those gene products as claimed in claims 2- 4 contradicts claim 1 and is outside the scope of claim 1.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2- 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims contradict a limitation of claim 1, as discussed above. Because of the contradictory requirements relating to orf E1A and E1B, the invention is so unclear that a meaningful examination of claims 2- 4 as written cannot be done.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The specification does not provide a repeatable method for obtaining the claimed modified adenovirus, and it does not appear to be readily available material. Applicant's deposit statement in the specification does not indicate the extent of availability of the deposit.

Since it is disclosed that the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the

patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that **all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent,** would satisfy the deposit requirements. See 37 CFR 1.808.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification discloses that the VORF6 virus is grown in 293 cells. 293 cells are known to complement adenovirus defective in the E1 region. There is no disclosure on how the E2 region is modified/ deleted and how this virus can be propagated. It is known that the E2 region is required for DNA replication and is required for late gene product expression (Gorziglia 1996, page 4176, column 2, middle- page 4177, column 1). There is no demonstration that the virus does not express all the gene products except E4 orf 6.

It is not clear that the virus of claim 5 meets the limitation of claim 1 "no other early or late gene products expressed" because it replicates in 293 cells. Gorziglia teaches that E2A is required for DNA replication. It is concluded that E2A must be

present in this virus for it to replicate in 293 cells. Therefore, it falls outside the scope of claim 1 and was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gorziglia (1999) and Leppard (J. of General Virology 1997, Vol 72, pages 2131- 2138).

Gorziglia discloses a modified adenovirus that is deleted in E1, E2a, E3, and all of E4 except orf 3 (see entire document).

The virus of Gorziglia (1999) is modified in all early region genes and only expresses E4 orf 3.

The cited reference differs from the claimed virus in that it expresses orf 3 and not orf 6 of E4. Gorziglia (1996, as discussed above) teaches that adenoviruses deleted in the E2a gene are lacking in DNA replication and late gene expression. Gorziglia (1999) is silent on expression of E2b, however, it would be expected absence of

expression of E2a also abolishes expression of E2b because E2A and E2B share common splicing in part of the mRNA.

Leppard discusses the roles of orf 3 and of orf 6 of E4. Either orf is capable of supplying essential adenoviral DNA replication functions and mutants deficient in expression of both orf 3 and orf 6 are substantially deficient in DNA replication (pages 2131- 2132).

It would have been obvious to substitute a functional equivalent, such as orf 6 for orf 3, with the reasonable expectation of success.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Armentano et al. (Human Gene Therapy 1995, Vol. 6, pages 1343- 1353).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill
Patent Examiner
January 13, 2003

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600